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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,344	08/23/2001	Vic Jira	22220-00003-US	8106

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/18/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/935,344	JIRA ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-16* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-9 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3, and 5-16 are pending in the application.

2. In the prior action, the Final action mailed on April 18, 2006, claims 1, 3, and 5-16 were pending in the application, with claims 1, 3, 5-9, and 13-16 under consideration and rejected, and claims 10-12 withdrawn as to non-elected inventions.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 18, 2006 has been entered.

In the Response of October 18, 2006, the Applicant amended claims 1, 3, and 5.

4. Currently, claims 1, 3, 5-9, and 13-16 are pending and under consideration.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **(Prior Rejection- Maintained)** Claims 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo et al. (U.S. 5,506,271). This claim has been amended to require that the claimed composition is a dry composition.

The Applicant traverses this rejection on two grounds. First, the Applicant asserts that there is no evidence that the heat inactivation taught in Meruelo preserves immunogenicity. However, as the Applicant noted on page 10 of the Response, Meruelo teaches a "process of inactivation of a virus with hypericin and related compounds [that] can preserve and enhance immunogenicity of the virus." thus, the reference teaches that the immunogenicity of the heat inactivated influenza antigen (here the inactivated virus) is maintained. The Applicant's assertion that the reference fails to teach how the immunogenicity is retained is therefore not found persuasive. Moreover, it is noted that the Applicant appears to consider the term "antigen" as limited to proteins. However, the examples in the present application indicate that the antigens of the application include not only inactivated individual proteins, but whole virus antigens inactivated according to the present methods. See e.g., page 28 lines 27-31, and example 15 at pages 62-63. Thus, the claims would appear to read on whole virus antigens inactivated according to the indicated method, such is disclosed by Meruelo.

The Applicant second argument in traversal is that the Meruelo reference fails to teach the claimed composition in that the reference does not teach a dry antigen. The Applicant asserts that because the reference does not teach a process for the drying of the antigen, the reference does not teach a dry antigen. This argument is not found persuasive. First, it is noted that the reference teaches that the compositions may be formulated for oral delivery, including embodiments wherein the antigens are formulated as oral tablets (i.e. mixed with solid, as

opposed to liquid ingredients to form a solid, as opposed to liquid, delivery formulation). Column 12. The reference teaches that such compositions may be made using conventional processes, indicating that drying processes as referred to by the Applicant were known in the art. Thus, the Applicant's assertion that the reference does not specifically teach such a drying process is not found persuasive in view of the teachings of the reference suggesting the use of a dry oral formulation.

For the reasons above, and the reasons of record, the rejection is maintained.

7. **(Prior Rejection- Maintained)** Claims 3, 5-9 and 13-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo as applied to claim 1 above, and further in view of either of Felici et al. (U.S. 5,994,083), or Ooyama et al. (EP 0 775 494). The Applicant traverses this rejection on the basis applied with respect to the Meruelo reference above, and on the basis that the additional teachings of Ooyama teach away from the claimed compositions, and that there is no motivation to combine the teachings of these references.

These arguments are not found persuasive. The arguments with respect to the teachings of Meruelo are not found persuasive for the reasons indicated above. With respect to the teachings of Ooyama, the Applicant asserts that the entire reference is directed to the prevention of antigen degradation by gastric juice. However, while the reference indicates that it is preferable to avoid denaturation of antigens, such is not a teaching away from the claimed invention, or the use of the compositions disclosed by Meruelo. First, it is noted that the teaching of Ooyama indicates a preference for avoiding such antigens, not a statement indicating that such antigens may not be used. Further, while Ooyama states a preference for avoiding the denaturing

of the antigen, the teachings of Ooyama are directed to the denaturing of antigens generally, and not the specific methods of antigen production described and suggested by the teachings of Meruelo. The teachings of Ooyama therefore fail to provide the necessary discouragement or discrediting of the teachings of Meruelo specifically to qualify as a teaching away from the use of such antigens. See e.g., MPEP 2123 II. Thus, the combined teachings of each of the cited references, those of ordinary skill in the art would still have had adequate motivation for the using any of the formulations disclosed by Felici or Ooyama in the for the antigens of Meruelo, which Meruelo indicates may be orally administered.

The additional teachings of Ooyama, regarding avoiding the degradation of the antigen by gastric juice, deal with a separate problem, and does not reflect on what those of ordinary skill in the art would have expected from the use of the antigens suggested by Meruelo.

For these reasons, and for the reasons of record, the rejection is maintained.

Conclusion

8. No claims are allowed.

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. The following prior art references are made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Sonntag et al., WO 00/24420 (translated as U.S. 2002/0001595). This reference teaches anti-viral compositions comprising heat-denatured antigens. However, the reference does not teach anti-influenza formulations, or the formulation of the antigens into dry oral formulations.
>
> Loibner et al., U.S. 2003/0143221. This reference teaches compositions comprising heat-treated antigen compositions, where the compositions are heated to a temperature of at least 80 degrees. However, the reference also teaches that, due to the contents of the composition, the antigenic proteins of the compositions are not denatured as required by the present claims. See e.g., page 2 paragraph [0015].

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

Bruce Campell

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